drug delivery segment, and where a ratio of the length of the tubes to the diameter of the tubes is about 5-25;

providing a therapeutic drug to the drug delivery segment for more than 24 hours; and

distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment to the brain of a patient.

REMARKS

This Amendment is submitted in response to the Office Action mailed June 18, 2002.

Rejection under 35 U.S.C. 112, second paragraph

Claims 1-29 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been amended in accordance with the Examiner's suggestions. Thus, it is respectfully submitted that rejection under 35 U.S.C. 112 has been rendered moot.

Rejection under 35 U.S.C. 102(b)

In the Office Action of June 18, 2002, claims 1-3, 5-6, 8, 11-12, 16-17, 19-21 and 23-24 were rejected under 35 U.S.C. 102(b) as being anticipated by Brucker et al. (U.S. Patent No. 5,462,521). This rejection is respectfully traversed.

Claim 1 of the present invention, as amended, claims a medical catheter having a drug delivery segment having a longitudinal axis and a length of about 0.1-1.0 cm along its longitudinal axis, and having an outside surface and an inside surface, the drug delivery segment defining tubes, each tube having a diameter and a length that extends radially from the inside

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surface to the outside surface, wherein [the] a ratio of the length of the tubes extending between the inside surface and the outside surface to the diameter of the tubes is about 5-25, the drug delivery segment [capable of] providing fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/minute with substantially equal fluid flow through each of the tubes.

Brucker teaches an ablation catheter that is electrically conductive. Indeed, Brucker states that the "channels 56, 58 are designed to communicate with path means 54 to provide a continuous evenly distributed fluid protective layer over the entire exterior surface 50 of metallic tip structure 26." Brucker, Col. 6, lines 24-27. Thus, Brucker does not teach a drug delivery segment. Brucker does not teach a drug delivery segment that provides fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/minute.

Brucker also does not disclose the length of the tubes in Figure 9, and thus does not teach a ratio of the length of the tubes to the diameter of the tubes. As a result, Brucker does not teach the ratio of the length of the tubes to the diameter of the tubes of about 5-25 as claimed in claim 1 of the present invention. This is an important aspect of the present invention because it has been discovered that the above ratio allows the drug delivery segment to provide "substantially equal flow through each of the tubes," which is also now claimed in amended claim 1.

Brucker is also silent on drug delivery rates. Thus, Brucker does not teach a drug delivery segment capable of providing fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/minute as claimed in claim 1 of the present invention.

Further, as noted above, Brucker does not teach "substantially equal flow through each of the tubes."

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Similarly, Brucker also does not teach the dependent claims 2-3, 5-6, 8, 11, 16-17, 19-21 and 23-24.

In view of the foregoing, the applicants respectfully request that the rejection under 35 U.S.C. 102(b) be withdrawn.

Rejection under 35 U.S.C. 103(a)

In the Office Action of June 18, 2002, claims 4, 7, 9-10, 12-15, 18, 25-27 and 29 were rejected 35 U.S.C. 103(a) as being unpatentable over Brucker et al. (U.S. Patent No. 5,462,521). This rejection is respectfully traversed.

For the above reasons that the rejection under 35 U.S.C. 102(b) should be withdrawn, so should the rejection under 35 U.S.C. 103(a) based on Brucker.

As stated above, Brucker teaches an ablation catheter that is electrically conductive. Indeed, Brucker states that the "channels 56, 58 are designed to communicate with path means 54 to provide a continuous evenly distributed fluid protective layer over the entire exterior surface 50 of metallic tip structure 26." Brucker, Col. 6, lines 24-27. Thus, Brucker does not teach a drug delivery segment. Brucker does not teach a drug delivery segment that provides fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/minute.

Brucker also does not disclose length of the tubes, and thus does not teach a ratio of the length of the tubes to the diameter of the tubes. As a result, Brucker does not teach the ratio of the length of the tubes to the diameter of the tubes of about 5-25 as claimed in independent claims 1 and 25 of the present invention. This is an important aspect of the present invention because it has been discovered that the above ratio allows the drug delivery segment to provide "substantially equal fluid flow through each of the tubes," which is also now claimed in amended

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claim 1. Claim 25 claims a method using the above ratio and having the step of "distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment."

Brucker is also silent on drug delivery rates. Thus, Brucker does not teach a drug delivery segment capable of providing fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/minute as claimed in claim 1 of the present invention.

Further, as noted above, Brucker does not teach "substantially equal flow through each of the tubes" as claimed in amended claim 1. Nor does Brucker teach the step in claim 25 of "distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment."

Similarly, Brucker also does not teach the dependent claims 4, 7, 9-10, 12-15, 18, 26-27 and 29.

In view of the foregoing, the applicants respectfully request that the rejection under 35 U.S.C. 103(a) based on Brucker be withdrawn.

In the Office Action of June 18, 2002, claims 22 and 28 were rejected 35 U.S.C. 103(a) as being unpatentable over Brucker et al. (U.S. Patent No. 5,462,521) in view of Lindsay et al. (U.S. Patent No. 4,863,441). This rejection is respectfully traversed.

For the above reasons that the rejection under 35 U.S.C. 102(b) and the rejection under 35 U.S.C. 103(a) based solely on Brucker should be withdrawn, so should the rejection under 35 U.S.C. 103(a) based on Brucker and Lindsay should be withdrawn.

Like Brucker, Lindsay does not disclose length of the tubes, and thus does not teach a ratio of the length of the tubes to the diameter of the tubes. As a result, Lindsay does not teach the ratio of the length of the tubes to the diameter of the tubes of about 5-25 as claimed in

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independent claims 1 and 25 of the present invention. This is an important aspect of the present invention because it has been discovered that the above ratio allows the drug delivery segment to provide "substantially equal flow through each of the tubes," which is also now claimed in amended claim 1. Claim 25 claims a method using the above ratio for "distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment."

Like Brucker, Lindsay is also silent on drug delivery rates. Thus, Lindsay does not teach a drug delivery segment capable of providing fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/minute as claimed in claim 1 of the present invention.

Like Brucker, Lindsay does not teach "substantially equal flow through each of the tubes" in amended claim 1, or a method including the step of "distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment" as claimed in claim 25.

Similarly, like Brucker, Lindsay also does not teach dependent claims 22 and 28. Thus, Lindsay does not satisfy the deficiencies in Brucker. There is also no teaching or suggestion to combine Brucker with Lindsay. Even if the proposed combination is proper, the combination does not result in the claimed invention.

Conclusion

In view of the foregoing, Applicants respectfully submit that this application is now in condition for allowance and request notification to that effect.

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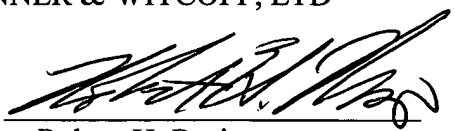
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**." The Examiner is invited to contact the undersigned should it be deemed necessary to facilitate prosecution of the application.

Respectfully submitted,
BANNER & WITCOFF, LTD

Dated: September 30, 2002

By: 

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"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

In the Claims:

Please amend claims 1, 6, 7, 12-13, 15-16, 21, 25-26, 28-29 and new claims 30-32 without prejudice.

1. (Amended) An implantable medical catheter comprising:

a proximal end having an opening for fluid containing a therapeutic drug,

a distal end, the distal end defining at least one opening, and

a drug delivery segment, implantable for more than twenty-four hours, at the opening defined by the distal end,

the drug delivery segment having a longitudinal axis and a length of about 0.1-1.0 cm along its longitudinal axis, and having an outside surface and an inside surface, the drug delivery segment defining tubes, each tube having a diameter and a length that extends radially from the inside surface to the outside surface, wherein [the] a ratio of the length of the tubes extending between the inside surface and the outside surface to the diameter of the tubes is about 5-25, the drug delivery segment [capable of] providing fluid containing a therapeutic drug to a target site at a rate of about 2 microliter/hour to 10 microliters/minute with substantially equal fluid flow through each of the tubes.

6. (Amended) The medical catheter of claim 1 wherein the inside surface of the drug delivery segment has a diameter of about [0.32] 0.03 inches, the outside surface of the drug deliver segment has a diameter of about [0.64] 0.06 inches, and the tubes defined by the drug delivery segment have a length of about [0.16] 0.02 inches.

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7. (Amended) The medical catheter of claim 1 wherein the number of the tubes defined by the drug delivery segment is about forty.

12. (Amended) The medical catheter of claim 9 wherein each of the rows is about 90 degrees from each adjacent row along the outside surface of the drug delivery element.

13. (Amended) The medical catheter of claim 1 wherein the number of the tubes defined by the drug delivery segment is about eighty.

15. (Amended) The medical catheter of claim 14 wherein each of the rows is about 45 degrees from each adjacent row along the outside surface of the drug delivery element.

16. (Amended) The medical catheter of claim 8 wherein [the] a distance from the proximal tube to the distal tube of the row is about 5.5 millimeters, and [the] a distance from the middle tube of the row to the distal end of the lumen of the drug delivery segment is about 5.0 millimeters.

21. (Amended) The medical catheter of claim 20 wherein the portion comprising a radiaopaque material is a band or bead to identify [the] a location of the drug delivery segment within a patient using X-ray, magnetic resonance imaging, or computerized axial tomography.

25. (Amended) A method for delivering a therapeutic drug comprising:

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forming a drug delivery segment having a longitudinal axis, the drug delivery segment having an outside surface and an inside surface,

forming tubes in the drug delivery segment, each tube having a diameter and a length that extends radially from the inside surface of the drug delivery segment to the outside surface of the drug delivery segment, and where [the] a ratio of the length of the tubes to the diameter of the tubes is about 5-25;

providing a therapeutic drug to the drug delivery segment for more than 24 hours[,]; and

distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment.

26. (Amended) The [medical catheter] method of claim 25 wherein the ratio of the length of the tubes to the diameter of the tubes is about 5.

28. (Amended) The method of claim 25 wherein the step of forming the tubes in the drug delivery segment results in forming tubes that taper as they extend from the outside surface of the drug delivery segment to the inside surface of the drug delivery segment.

29. (Amended) The method of claim 25 wherein the step of forming the tubes in the drug delivery segment results in forming tubes that are non-tapered as they extend from the outside surface of the drug delivery segment to the inside surface of the drug delivery segment.

30. (New) An implantable medical system comprising:

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a therapeutic drug source, the therapeutic drug source in fluid communication with a catheter,

the catheter having a proximal end having an opening for fluid containing a therapeutic drug from the therapeutic drug source, a distal end, the distal end defining at least one opening, and a drug delivery segment, implantable for more than twenty-four hours, at the opening defined by the distal end, the drug delivery segment having a longitudinal axis and a length of about 0.1-1.0 cm along its longitudinal axis, and having an outside surface and an inside surface, the drug delivery segment defining tubes, each tube having a diameter and a length that extends radially from the inside surface to the outside surface, wherein a ratio of the length of the tubes extending between the inside surface and the outside surface to the diameter of the tubes is about 5-25, the drug delivery segment providing a therapeutic drug from the therapeutic drug source to a target site at a rate of about 2 microliter/hour to 10 microliters/minute with substantially equal fluid flow through each of the tubes.

31. (New) A method for delivering a therapeutic drug comprising:

forming a drug delivery segment having a longitudinal axis, the drug delivery segment having an outside surface and an inside surface,

forming tubes in the drug delivery segment, each tube having a diameter and a length that extends radially from the inside surface of the drug delivery segment to the outside surface of the drug delivery segment, and where a ratio of the length of the tubes to the diameter of the tubes is about 5-25;

providing a therapeutic drug to the drug delivery segment for more than 24 hours from an intraparenchymal catheter; and

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distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment.

32. (New) A method for delivering a therapeutic drug comprising:

forming a drug delivery segment having a longitudinal axis, the drug delivery segment having an outside surface and an inside surface,

forming tubes in the drug delivery segment, each tube having a diameter and a length that extends radially from the inside surface of the drug delivery segment to the outside surface of the drug delivery segment, and where a ratio of the length of the tubes to the diameter of the tubes is about 5-25;

providing a therapeutic drug to the drug delivery segment for more than 24 hours; and

distributing the therapeutic drug in approximately equal amounts through the tubes defined in the drug delivery segment to the brain of a patient.

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